



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,410	01/25/2001	Christian Huber	P-576	6186

25732 7590 10/11/2002

JOHN F. BRADY
TRANSGENOMIC, INC.
2032 CONCOURSE DRIVE
SAN JOSE, CA 95131

EXAMINER

THERKORN, ERNEST G

ART UNIT	PAPER NUMBER
----------	--------------

1723

DATE MAILED: 10/11/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,410

Applicant(s)

HUBER

Examiner

THEKORN

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sept 30, 2002
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-76, 79-92, 95, and 97 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-76, 79-92, 95, and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1723

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-76, 79-92, 95, and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,355,791 and allowed application no. 09/848,385 in view of in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457). At best, the claims differ from each of U.S. Patent No. 6,355,791 and allowed application no. 09/848,385 in reciting use of a fused silica capillary, the clarity of covalent bonding, and a size of less than one millimeter in diameter. Peters

Art Unit: 1723

(Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns is the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis. It would have been obvious to use a fused silica column in each of U.S. Patent No. 6,355,791 and allowed application no. 09/848,385 because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious that the polymer is covalently bound because Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. It would have been obvious to use a column less than 1 millimeter in diameter because Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns is the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis.

Claim 74 is rejected under 35 U.S.C. 101 as double patenting claim 73 because claim 74 has the same scope as 73.

Art Unit: 1723

Claim 74 is rejected under 35 U.S.C. 112, second paragraph, as being an improper dependent claim because it does not further limit claim 73.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51-76, 79-92, 95, and 97 are rejected under 35 U.S.C. 102(A) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gusev, Journal of Chromatography, 1999, pages 273-290. The claims are considered to read on Gusev, Journal of Chromatography, 1999, pages 273-290. However, if a difference exists between the claims and Gusev, Journal of Chromatography, 1999, pages 273-290, it would reside in optimizing the elements of Gusev, Journal of Chromatography, 1999, pages 273-290. It would have been obvious to optimize the elements of Gusev, Journal of Chromatography, 1999, pages 273-290 to enhance separation.

Claims 57-58 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gusev, Journal of Chromatography, 1999, pages 273-290 in view of Peters (U.S. Patent No. 5,929,214). At best, the claims differ from Gusev, Journal of Chromatography, 1999, pages 273-

Art Unit: 1723

290 in reciting channels sufficiently large to allow convective flow. Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith. It would have been obvious to have sufficiently large channels to allow convective flow in Gusev, Journal of Chromatography, 1999, pages 273-290 because Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gusev, Journal of Chromatography, 1999, pages 273-290 in view of Girot (U.S. Patent No. 6,045,697). At best, the claim differs from Gusev, Journal of Chromatography, 1999, pages 273-290 in reciting use of a tetrahydrofuran porogen. Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen. It would have been obvious to use tetrahydrofuran as a porogen in Gusev, Journal of Chromatography, 1999, pages 273-290 because Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gusev, Journal of Chromatography, 1999, pages 273-290 in view of either Huber (Anal. Chem. 1998, 70, 5288-5295) or Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997). At best, the claim differs from Gusev, Journal of Chromatography, 1999, pages 273-290 in reciting use of a mass spectrometer. Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range. Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses

Art Unit: 1723

that electrospray mass spectrometry is a gentle sensitive method of analysis. It would have been obvious to use mass spectrometry in Gusev, *Journal of Chromatography*, 1999, pages 273-290 either because Huber (*Anal. Chem.* 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range or because Griffey (*Journal of Mass Spectrometry*, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis.

Claims 51-66, 71, 73-76, 79-85, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (*Anal. Chem.* 1997, 69, 3646-3649), Huang (*Journal of Chromatography* 788 (1997) 155-164), and Tomer (*Mass Spectrometry Reviews*, 1994, 13, 431-457). At best, the claims differ from each of Frechet (U.S. Patent No. 5,344,310) and Hatch (U.S. Patent No. 6,238,565) in reciting use of a fused silica capillary, the clarity of covalent bonding, and a size of less than one millimeter in diameter. Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (*Anal. Chem.* 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Huang (*Journal of Chromatography* 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. Tomer (*Mass Spectrometry Reviews*, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns is the trend in chromatography because of improved concentration detection limits and the small

Art Unit: 1723

amounts of sample available for analysis. It would have been obvious to use a fused silica column in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious that the polymer is covalently bound because Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. It would have been obvious to use a column less than 1 millimeter in diameter because Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns is the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis.

Claims 67-70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Huang (Journal of Chromatography 788 (1997) 155-164). At best, the claims differ from each of Frechet (U.S. Patent No. 5,344,310) and Hatch (U.S. Patent No. 6,238,565) in reciting use of a fused silica capillary and the clarity of covalent bonding. Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Huang (Journal of Chromatography 788 (1997) 155-164) (the

Art Unit: 1723

paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. It would have been obvious to use a fused silica column in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious that the polymer is covalently bound because Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer.

Claims 86-92 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457). At best, the claims differ from each of Frechet (U.S. Patent No. 5,344,310) and Hatch (U.S. Patent No. 6,238,565) in reciting use of a fused silica capillary and a size of less than one millimeter in diameter. Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns is the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis. It would have been obvious to use a fused silica column in either Frechet (U.S. Patent

Art Unit: 1723

No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious to use a column less than 1 millimeter in diameter because Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns is the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis.

Claims 57-58 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) as applied to claims 51-66, 71, 73-76, 79-85, and 95 above, and further in view of Peters (U.S. Patent No. 5,929,214). At best, the claims differ from either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) in reciting channels sufficiently large to allow convective flow. Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith. It would have been obvious to have sufficiently large channels to allow convective flow in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of

Art Unit: 1723

Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) because Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) as applied to claims 86-92 and 97 above, and further in view of Girot (U.S. Patent No. 6,045,697). At best, the claim differs from either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) in reciting a tetrahydrofuran porogen. Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen. It would have been obvious to use tetrahydrofuran as a porogen in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) because Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) as applied to claims 51-66, 71, 73-76,

Art Unit: 1723

79-85, and 95 above, and further in view of either Huber (Anal. Chem. 1998, 70, 5288-5295) or Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997). At best, the claim differs from either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) in reciting use of a mass spectrometer. Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range. Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis. It would have been obvious to use mass spectrometry in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) either because Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range or because Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis.

The restriction requirement has been reconsidered, deemed proper, and made final for the reasons of record.

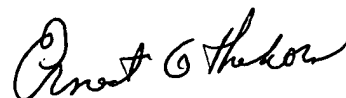
Any inquiry concerning this communication should be directed to E. Therkorn at

Application/Control Number: 09/770,410

Page 12

Art Unit: 1723

telephone number (703) 308-0362.

A handwritten signature in cursive script, reading "Ernest G. Therkorn".

Ernest G. Therkorn
Primary Examiner
Art Unit 1723

EGT/12
October 9, 2002